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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,534	09/26/2001	Stefan Bracht	F-7125	9613

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,534

Applicant(s)

BRACHT, STEFAN

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 14-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Acknowledgement of Papers Received: Information Disclosure Statement and Preliminary Amendment dated 9/26/01 and Preliminary Amendment dated 1/8/02

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 3, the claim is contains confusing language that makes the scope of the claim unclear. The claim recites that “the monoterpene ketone is a pure enantiomer” but does not recite what the ketone is an enantiomer of. The examiner is unclear as to the scope of the claim, and therefore the claim is rendered indefinite. Canceling or amending the claim can overcome this rejection.

4. Regarding claim 16, the claim is dependent upon previously canceled claim. The claim is confusing because it is not clear to the examiner what the scope of the claimed invention is. Being dependent upon a canceled claim renders the claim indefinite. Canceling or amending the claim can overcome this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al (USPN 5820877). Claims 1, 2 and 14 are drawn to a transdermal therapeutic system (TTS) comprising a backing layer and nicotine containing pressure-sensitive adhesive layer, protected by a film. The TTS of the claim invention further comprises either an essential oil or a monoterpene ketone.

Yamaguchi et al discloses a TTS with a backing layer, pressure-sensitive drug zone, protected by a separate layer. The reference teaches that the drug can be nicotine, and that the formulation also comprises 1-menthol (Abstract; col. 4, lin. 18; col. 4, lin. 50 – 54; claims). These disclosures along with other leave the claims anticipated.

7. Claims 1, 2, 5 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Majeti (USPN 5599554). The claims are drawn to a TTS comprising nicotine, and monoterpene ketones. The claims recite that the concentration of nicotine is between 0.5 and 2.0% wt.

Majeti discloses a TTS comprising a backing layer, menthol, and nicotine in a concentration between 1.0 and 2.0% wt (Abstract; col. 5, lin. 18 – 23; col. 6, lin. 6 – 21; Examples I and II). These disclosures, along with others, render the claims anticipated.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-5, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al (USPN 5820877) and Majeti et al (USPN 5599554) in view of Baker et al (USPN 5362496). The claims are drawn to a TTS comprising a backing layer and either a monoterpene ketone or a mint oil. The claims recite that as an essential oil, spearmint is to be used.

It has been discussed above how Yamaguchi and Majeti meet the limitations of the claimed invention. Baker discloses a formulation comprising essential oils and nicotine. The formulation of the reference can be formulated into transmucosal form comprising spearmint and other odor and taste masking oils. Baker further discloses a TTS comprising a backing later and a pressure-sensitive adhesive (col. 6, lin. 50 – 67; col. 7, lin. 29 – 34; col. 16, lin. 9 – 15; col. 20, 26 – 33).

Though the reference does not disclose peppermint oil specifically in the formulation, essential oils, and other enantiomers were disclosed such as menthol, carvone and the like. With this substitution taken into consideration, the recitation of peppermint oil would be merely a selection of species, and not patentably distinct from the prior art. Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of Yamaguchi, Majeti and Baker. A skilled artisan would be motivated to combine the formulation of Majeti with the TTS of Yamaguchi in order to provide suitable, stable and protective delivery of the nicotine formulation. Using the backing layer, pressured-sensitive adhesive layer, and protective film of Yamaguchi to deliver the nicotine and monoterpene ketone containing formulation transdermally. A skilled artisan would be equally motivated to combine the formulation of Majeti with the TTS of Yamaguchi. Again Yamaguchi would provide a suitable, stable, and protective delivery method for the nicotine, and essential oil containing formulation. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings in this way with an expected result of a TTS comprising a pressure-sensitive adhesive, backing layer, protective film, and a formulation comprising nicotine and equally effective essential oils. This TTS would be expected to suitable for useful in nicotine suppression therapies.

11. Claims 6-8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al (USPN 5820877) and Majeti et al (USPN 5599554) and Baker et al (USPN 5362496) all in view of Brisken et al (USPN 3559655) and DeFoney et al (USPN 4039653). The claims are drawn to a process for masking the odor of nicotine in a TTS using essential oils or monoterpene ketone derivatives thereof. The claims go on to recite that the essential oil is

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peppermint, and the monoterpene ketone is selected from a group comprising menthone, pipertone, or carvone.

As previously discussed above the combination of the teachings of Yamaguchi, Majeti and Baker render the claimed invention obvious. It is the position of the examiner that this combination also renders the claimed process obvious, by the inherent properties of the constituents. It is known in the art that mint oil and extracts (monoterpene ketone included) have odor and taste masking properties. As seen in DeFoney et al (col. 9, lin. 15 – 20) and Briskin (col. 7, lin. 1 – 5) it is recognized in the art that these substances mask odors when introduced into formulations. Their presence in the combination discussed above, would inherently mask the odor of the surrounding constituents. Though not disclosed by the reference, given the inherent odor-masking properties of mint oils, and extracts, one of ordinary skill in the art would have been motivated to follow the knowledge in the art in order to mask the odor of the constituents of the TTS. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the knowledge in the art with the expected result of a TTS comprising a suitable backing, and protective layer, useful nicotine suppression therapy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-308-1235 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-5014.

Micah-Paul Young
Examiner
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MPY
May 31, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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